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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,819	03/18/2004	Rae Ellen Syverson	KCC 4749.1 (K-C 16,858.1)	7018
321	7590	06/16/2005	EXAMINER	
SENNIGER POWERS LEAVITT AND ROEDEL ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			CHANNAVAJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/803,819

Applicant(s)

SYVERSON ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 5, 12, 13 and 26-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11 and 14-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2-4-05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Receipt of response to election requirement dated 4-27-05 and IDS dated 2-4-05 is acknowledged.

Applicant's election of R2, R3 and R4 is H and sub-species, ether in the reply filed on 4-27-05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicants state that claims 1-4 and 6-60 are readable on the elected species and claims 1-11 and 14-38 are readable on sub-species, ether. However, a careful review of the instant claims shows that only claims 1-4, 6-11 and 14-25 read on elected species because the second active agent claimed in each of the independent claims 26, 39, 40, 48 and 55 read on non-elected sub-species i.e., second active agents having a compound with a glycosidic, ester, amide and an amine bond. Accordingly, claims 1-4, 6-11 and 14-25 are considered for examination and claims 5, 12, 13 and 26-55 are withdrawn from further consideration.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-11 and 14-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over a combination n of US 6,416,779 to D'Augustine et al (D'Augustine) and US 5,895,643 to Hoppe et al (Hoppe) or Hoppe in view of D'Augustine.

D'Augustine teaches a method for treating intravaginal or transvaginal bacterial, fungal, viral or parasitic infections comprising a device that contains a pharmaceutically effective amount of an antimicrobial, antifungal, antiviral or antiparasitic agent.

D'Augustine teaches the device in the form of a non-absorbent tampon or tampon-like device, intravaginal sponge or ring etc (col. 2, summary of invention, col. 3 & col. 7, lines 1-29, brief description of figure 15). D'Augustine fails to teach the claimed active agents of the instant invention.

Hoppe teaches deodorizing and anti-microbial compositions for use in suppressing unpleasant body odor due to decomposing. The composition of Hoppe comprises a combination of phenoxyethanol that reads on instant active agent of claim 1 (col. 4, lines 61-67, col. 5, lines 1-4). Hoppe teaches a combination of phenoxyethanol, glycerol monoester of a fatty acid and polyethylene glycol-20 ether (reads on the elected sub-species). In particular, examples 5 recite ether containing compound and one of the

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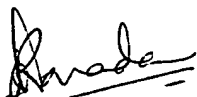
compositions A-F that contains phenoxy ethanol. Hoppe teaches various percentages of the active agents in examples and col. 5, lines 56-67. Hoppe teaches applying the composition topically in the form of soap, lotion, spray, gel etc (col. 5) but not a vaginal device. However, Hoppe teaches the composition for effective odor prevention and suggests phenoxyethanol as a very safe, non-toxic antibacterial agent. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to apply the safe, non-toxic, antibacterial and odor preventing composition of Hoppe (containing claimed combination of phenoxyethanol with an ether compound) on the vaginal device such as a tampon or tampon-like device of D'Augustine with an expectation to provide a highly effective antibacterial and treatment for reducing bacterial infections in the vaginal area and also reduce the odor because Hoppe suggests that the combination of phenoxyethanol with ether and monolaurate provides highly synergistic anti-bacterial treatment by odor producing enzyme inhibition as well as bacterial killing and that is safe, easy to handle and well tolerated by mucosal membranes (col. 3). Further, it would have been within the scope of a skilled artisan to optimize the amount of phenoxyethanol and other active ingredients (of Hoppe) that are to be applied on to the vaginal device (of D'Augustine) with an expectation to achieve an optimum effect of the composition. Hoppe does not teach the specific ether compounds of claim 21. However, absent criticality, it would have been within the scope of a skilled artisan to choose a suitable ether compound in combination with phenoxyethanol and still achieve the desired antibacterial effect because Hoppe recognizes the antibacterial and deodorizing effect of ethers in general.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615

June 13, 2005